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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,875	08/21/2003	Ying-Fei Wei	PF174USD2	7047

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EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,875	WEI ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25 and 31-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25 and 31-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 and 26-30 have been cancelled and claims 31-44 have been newly added. Claims 25 and 31-44 are under consideration.

It is noted that applicant submitted an amended specification on 10/20/03 to include changes made in the parent application.

Priority

Applicant is requested to update the status of the applications listed in the first line of the specification.

Information Disclosure Statement

The Genbank Accession Nos. listed on the IDS submitted 1/5/05 have been lined through because these are incomplete citations.

Specification

Applicant is requested to amend the brief description of the drawings in the specification to reflect the numbered subparts.

The amendment filed 6/12/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Amendments to page 5, line 3, paragraph [0027] of the specification.

Applicant has altered amino acid end point ranges for different domains of SEQ ID NO: 2 as disclosed on page 5.

The arguments presented by applicant have been considered but are not persuasive.

Applicant argues that the original sequence listing for parent application PCT/US95/06386 numbered SEQ ID NO: 2 using negative numbers for the signal sequence (-45 through –1) and that parent applications 08/930,564 and 09/227,853 (now U.S. Patent Nos. 6,410,506 and 6,642,006, respectively) altered the numbering of SEQ ID NO: 2 to remove the negative numbering and to begin numbering of SEQ ID NO: 2 at +1. This change was made in a substitute or amended sequence listing. However, the text of PCT/US95/06386 on page 6 is the same as that of the originally filed instant specification. PCT/US95/06386 does not refer to the negative numbering of SEQ ID NO: 2. The positions disclosed on PCT/US95/06386 on page 6 are considered to reflect the sequence disclosed in SEQ ID NO: 2 numbering from +1 at the first position rather than –45. This would have been a fair interpretation of the PCT/US95/06386 specification when read by one of ordinary skill in the art at the time of the invention. Thus, it reflects the present sequence listing for SEQ ID NO: 2 which explicitly numbers from +1 at the first position and does not provide basis for the altered ranges disclosed by applicant.

Example 2 discusses nucleotide ranges with respect to SEQ ID NO: 1. The text indicates that particular ranges of SEQ ID NO: 1 include or exclude certain domains but does not identify any end points by either nucleotide or amino acid. Note that the instant specification on page 29 indicates that the putative soluble portion of the polypeptide corresponds to nucleotides 1100-1248 of SEQ ID NO: 1. As shown in SEQ ID NO: 1, this would include nucleotides encoding amino acids 260 through 374 as well as noncoding nucleotides. The disclosure makes no mention of the primers with respect to the sequence of Figure 1 and the numbering of SEQ ID NO: 1 has not changed when the disclosure of PCT/US95/05386 and the instant application are

compared. This disclosure of the putative soluble portion is inconsistent with the original text on page 5 as it appears to include the transmembrane domain.

Inconsistencies cannot be characterized or corrected as obvious typographical errors unless the correction to the obvious typographical error is also clear. The originally filed specification does not make clear that the changes made by applicant are the obvious correction to any inconsistency.

Review of parent application (US 6,642,006 and US 6,410,506) with respect to these points reveals that no similar amendments appear to have been proposed and no declaration evidence or other arguments appear to have been presented. The sequence listing of the instant application was transferred from the parent application. The instant drawings also correspond to those in the parent applications.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 25 and 31-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter and written description rejection.

Claim 25 has been amended to be directed to a method for the treatment of a patient having need to inhibit TGFα-HII comprising administering an antibody capable of binding to a polypeptide comprising a member selected from the group consisting of amino acid ranges 1-

374, 46-374, 1-309, 46-309, and 260-309 of SEQ ID NO: 2 as well as fragments thereof (see parts (g)-(i)).

Basis is not seen for the claimed methods.

No basis is seen for administering chimeric antibodies (claim 41), humanized antibodies (claim 42), single-chain antibodies (claim 43), and Fab fragments (claim 44) in the specification.

Original claim 25 depended from claim 22 that was directed to a compound that inhibits activation of the polypeptide of claim 19. These claims did not contemplate administering therapeutic antibodies directed to particular parts of SEQ ID NO: 2 and no basis is seen in the specification for the presently claimed method. Furthermore, although original claim 19 does list the ranges 1-374 and 46-374 as well as a polypeptide encoded by the cDNA contained in ATCC Deposit No. 97160, no basis is seen for the other named ranges. (See also new matter objection to the specification above with respect to these amino acid ranges.) A discussion as to what amino acids are identified as the leader sequence or transmembrane sequence cannot be construed as providing basis for claiming antibodies that specifically bind to particular fragments or administering such antibodies for particular therapeutic purposes. A fair reading of the specification would not indicate that these antibodies were contemplated as being part of the invention. Furthermore, part (f) is considered to mean any fragment of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 97160 in view of the recitation "a polypeptide."

The information concerning the deposit on page 6 of the specification does not make clear what cDNA sequence is actually contained in ATCC deposit number 97160. The disclosure implies that only the mature sequence is contained. Applicant asserted in the

prosecution of parent application 09/227,853 that DNA encoding the full-length sequence of SEQ ID NO: 2 is present in the recited deposit.

It is noted that the specification has been amended to change the date of deposit of ATCC 97160 from 15 May 1995 to 24 May 1995. Applicant has altered the originally filed specification at pages 4, 28, 29, and 32 with respect to deposit information without supplying the supporting documentation from parent application 09/227,853. It is permissible to amend the specification to include post-filing date deposit information with a corroborating statement (see MPEP 2406.02) establishing that the biological material disclosed in the specification was in fact the material deposited at the later date. Applicant must supply copies of the same evidence presented in 09/227,853 to complete the instant application. These changes are considered to be new matter in the absence of this evidence.

Note that because claims 25 and 36 recite ATCC 97160, this deposit is required for enablement of these claims.

Claims 25 and 31-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

The specification fails to identify those patients having need to inhibit TGFα-HII. It is not known what characteristics or medical conditions such patients must possess.

The specification fails to identify any antibodies that bind to any portion of SEQ ID NO: 2 that are capable of inhibiting TGFα-HII either in vitro or in vivo. The specification and prior art of record fail to provide any evidence that there is a correlation between any in vitro antibody binding and any in vivo inhibition of TGFα-HII for any therapeutic purpose.

The specification fails to identify any fragments of SEQ ID NO:2 (including any 30 and 50 contiguous amino acid ranges) or any polypeptides at least 70% identical to SEQ ID NO: 2 that could be used to generate antibodies that have the property of in vivo inhibition of TGFα-HII for any therapeutic purpose.

In the absence of such guidance or direction, it would constitute undue experimentation to practice the invention as claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen
Primary Examiner
Art Unit 1647

mpa